



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2022-0044]

**CDC Recommendations for Hepatitis B Screening and Testing -
United States, 2022; Request for Comment**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on proposed updated recommendations for hepatitis B virus (HBV) infection screening and testing (Proposed Updated Recommendations), including hepatitis B screening at least once in a lifetime for persons 18 years of age and older, using a three-test panel. The Proposed Updated Recommendations also expand existing risk-based testing recommendations to include the following populations, activities, exposures, or conditions associated with increased risk for HBV infection: persons currently or formerly incarcerated in a jail, prison, or other detention

setting; persons with a history of sexually transmitted infections or multiple sex partners; and persons with a history of hepatitis C virus infection. The Proposed Updated Recommendations are intended to inform the practices of and care by U.S. healthcare providers and are based on scientific evidence of the effectiveness and economic value of screening to diagnose current HBV infection among adults in the United States.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0044, by either of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of Viral Hepatitis, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop U12-3, Atlanta, GA 30329, Attn: Docket No. CDC-2022-0044.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information

provided. **Do not submit comments by email; CDC does not accept comments by email.** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Erin Conners, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop U12-3, Atlanta, GA 30329; Telephone: 404-639-8000; Email: DVHpolicy@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data related to any of the Proposed Updated Recommendations or supporting evidence. In addition, CDC invites comments specifically on the following questions:

- Based on the evidence presented in the full recommendations document (see the Supporting and Related Materials tab in the docket), does the evidence support the Proposed Updated Recommendations for HBV infection screening and testing? If not, please state the reason why and, if available, provide additional evidence for consideration.
- Are CDC's Proposed Updated Recommendations (see

Supporting and Related Materials) clearly written?

If not, what changes do you propose to make them clearer?

- If implemented as currently drafted, do you believe the Proposed Updated Recommendations would result in a reduction in HBV infections and associated health and financial consequences (e.g., patient and healthcare costs to treat chronic hepatitis B) in the United States? If not, please provide an explanation and supporting data or evidence.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure.

Comments will be posted on <https://www.regulations.gov>.

Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold,

submissions containing private or proprietary information such as Social Security numbers, medical information,

inappropriate language, or duplicate/near duplicate examples

of a mass-mail campaign. **Do not submit comments by email.**

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Background and Brief Description

Hepatitis B virus (HBV) is transmitted via blood or sexual contact. Persons with chronic HBV infection are at increased risk for cirrhosis and liver cancer and require medical care (Schillie et al., 2018). National health survey data indicate that about 880,000 people were living with HBV infection in the United States during 2013-2018, with modeled data putting that estimate at 1.89 million (Roberts, Ly, et al., 2021; Wong et al., 2021). Testing is the first step in accessing treatment, but an estimated two-thirds of people living with hepatitis B in the United States during 2013-2018 were unaware of their HBV infection (Kim et al., 2013). Despite the availability of highly effective hepatitis B vaccines that can prevent development of subsequent acute and chronic liver disease, 70 percent of adults in the United States self-reported they were unvaccinated as of 2018 (Lu et al., 2021). National surveillance data reveal that during 2011-2019, rates of reported acute hepatitis B steadily increased among persons aged 40-49 and 50-59 years (CDC Viral Hepatitis Surveillance, 2021). Among the acute HBV cases reported to CDC in 2019, injection drug use was the most common risk factor (CDC Viral Hepatitis Surveillance, 2021). Rates of

newly reported chronic hepatitis B were highest among persons aged 30-49 years, Asian/Pacific Islander persons, and Black/African American persons in 2019 (CDC Viral Hepatitis Surveillance, 2021). Providing a framework to reach the World Health Organization (WHO) viral hepatitis elimination goals, the Viral Hepatitis National Strategic Plan for the United States calls for an increase in the proportion of people with HBV infection who are aware of their infection from a baseline of 32 percent during 2013-2016 to 90 percent by 2030 (Department of Health and Human Services, 2020). In support of this goal, CDC used current evidence to update its previous 2008 recommendations for testing and management for people with chronic hepatitis B in the United States.

As described in the recommendation document found in the Supporting and Related Materials tab of the docket, these recommendations supplement previously published CDC recommendations for testing and identifying persons with chronic HBV infection in the United States published in 2008 (Weinbaum et al., 2008). They do so by adding hepatitis B screening at least once in a lifetime for persons aged 18 years of age and older and specifying the use of the three-test panel during screening to identify persons who: 1) have a current HBV infection, 2) have resolved infection and who may be susceptible to

reactivation, 3) are susceptible and need vaccination, or
4) are vaccinated.

Dated: March 30, 2022.

Angela K. Oliver,

Executive Secretary,

Centers for Disease Control and Prevention.

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